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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,524	09/29/2006	Hans Naegele	20802/0205146-US0	1315
7278	7590	10/16/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER YANG, ANDREW	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,524

Applicant(s)

NAEGERL, HANS

Examiner

Andrew Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/17/2007, 9/29/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, it is unclear how the intermediate can have a non-positive connection between the outer elements since it previously states in claim 15 that the intermediate element positively joins the outer elements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 15, 18, 19, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Viart et al. (U.S. Patent No. 6682562).

Viart et al. discloses an artificial intervertebral disc 1 with two outer elements 2, 3 and an intermediate element 5. The outer elements 2, 3 have a contour 12 where the intermediate element 5 is in contact and thereby joining the outer elements 2, 3 (Column 3, Lines 66-67 and Column 4, Lines 1-4). The contour 12 is part of the inner surface of the outer elements 2, 3 that is in frictional contact with the intermediate element 5 to control and restrict axial rotation and also creates a non-positive connection between the outer elements 2, 3 (Column 4, Lines 16-21). Furthermore the intermediate element is made of polyethylene (Column 3, Lines 46-47).

Claims 15-17, 20-27, and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuras (U.S. Patent No. 7169181).

Kuras discloses an artificial intervertebral disc 110 with two outer elements 120, 140, and an intermediate element 160. The two outer elements 120 each have a concave contour 124, 144 and can also be considered recesses. The two outer elements 120, 140 have anchoring elements in the form of pins 126, 156 disposed on a side facing adjacent vertebral bodies. The outer surfaces of the outer elements are coated with a biocompatible material in the form of sintered beads 132, 158 and include titanium since the outer elements are made of titanium (Column 4, Lines 48-50).

The intermediate element 160 is positively joined to the outer elements 120, 140 in the contours 124, 144 by adhesion (Column 5, Lines 47-54). The contours are oversized as seen in Figure 8 since the outer elements over hang the intermediate

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element 160. The patient moving causes compression of the implant 110, and compression of the intermediate element 160 allows a defined deformation of the disk (Column 5, Lines 56-65). The intermediate element 160 has a closed annular shape (Figure 8) in the form of an oval. The intermediate element 160 defines an annular central axis extending between the out elements 120, 140 and the cross section taken cross wise to the axis is oval (Figure 8). Furthermore, the cross-sections taken along the central axis differ in size such that it widens as the cross sections are taken along the central axis. The intermediate element is made of a polymer (Column 5, Lines 30-31).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Yang whose telephone number is 571-272-3472. The examiner can normally be reached on 8:00am-5:30pm: Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.Y.
10/14/2007



EDWARD C. ROBERT
SUPERVISORY PATENT EXAMINER